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Wegwerf-Biopsie-Zange

Pince de biopsie à usage unique

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EP-A-0 317 526
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Description**FIELD OF THE INVENTION**

The invention relates to a biopsy device comprising an elongate flexible tube (10) having a proximal end and a distal end; a pair of biopsy jaws (20) each having a proximal end and a distal end, the proximal ends of the biopsy jaws (20) being pivoted about a pivot (48) for closing inward and opening outward movement; an actuating member (14) extending through the tube (10) and being connected at its distal end to the pivot (48), the actuating member (14) being controllable from the proximal end of the device to be movable proximally or distally within the tube (10); the jaws (20) having inner (68) and outer (70) camming surfaces; and the distal end of the tube (10) having surfaces engageable with the inner (68) and outer (70) camming surfaces on the jaws (20) to cause the jaws (20) to open when the actuating member (14) is moved in one direction and to close when the actuating member (14) is moved in the opposite direction.

BACKGROUND OF THE INVENTION

When making an endoscopic examination of a particular site in a patient's body, it is common for the physician to take at least one tissue sample from that site for analysis. A variety of such devices for taking of small tissue samples are in use. In general, such biopsy devices include a small diameter elongate catheter-like instrument adapted to be passed through a lumen in the endoscope, the device being longer than the endoscope so that its distal end can extend out of the distal end of the endoscope. The distal end of the device typically is provided with a pair of sharp jaws that can be opened and closed to cut and draw away a small sample of tissue to be investigated. The opening and closing of the jaws is controlled manually by the physician by manipulating controls at the proximal end of the device.

Such endoscopic biopsy procedures involve repeated insertion and removal of the device through the narrow endoscope channel when it is necessary to take multiple biopsies. The device must be sufficiently rugged to withstand such repeated use yet must be constructed so that it will not cause damage to any of the parts of the endoscope as it is advanced through the endoscope channel.

Among the difficulties presented with such devices is that they typically are relatively expensive, partly because of the intricate work required to manufacture the miniature jaws and jaw actuating mechanisms. Additionally, the cutting edges of the jaw tend to become dull with use and require periodic sharpening, a procedure that involves considerable skill and a high degree of care because of the miniature size of the jaws. Very slight errors in sharpening procedure can impair seriously the effectiveness of the jaws. Often, it is only pos-

sible to sharpen such a device a few times before its dimensions are so changed that it is no longer effective. When that occurs, it is common practice to replace the entire device. Also among the difficulties presented by such endoscopic biopsy devices is that they are difficult to clean and sterilize. The jaw mechanisms define numerous crevices. Additionally, the elongate body of the device is made from a highly flexible tightly wound helical coil which provides numerous crevices for retaining debris or contaminants and the like.

Devices of the above mentioned type are known from WO-A-90/01297 and EP-A-380874. These devices have a relatively short stroke for the action wire because their inner and outer camming surfaces extend only to the pivot pin that connects the two jaws. Therefore the physician has to exercise a high pulling force on the control wire to sever a tissue sample. It is believed that there is a need for a low cost, simple, disposable endoscopic biopsy device which comprises a longer stroke for the actuation wire than the known devices to allow the physician to sever a tissue sample with less pulling force.

SUMMARY OF THE INVENTION

The device includes an elongate flexible tubular catheter shaft and a control wire that extends through the catheter and is connected at its proximal end to an actuation means by which the physician may pull or push on the wire. The distal end of the device carries a pair of jaws each of which has at its end a sharp rimmed cup so that when the jaws are brought together, they may sever and retain a sample of tissue. Unlike the prior art biopsy devices, the present invention, embodies a simple and inexpensive arrangement for the biopsy jaws that is free of complex linkages and multiple hinge points. The device of the above mentioned type has only a single hinge point and is according to the invention characterized in that each of the jaws has an arm having a proximal segment, an outwardly offset intermediate segment extending from the distal end of the inner segment, and a distal segment extending from the distal end of the intermediate segment and that the inner and outer camming surfaces are formed on the inwardly and outwardly facing surfaces of the intermediate segment.

It is among the general objects of the invention to provide endoscopic biopsy devices having biopsy jaw arrangements that are of relatively simple inexpensive design.

Another object of the invention is to provide an endoscopic biopsy device of sufficiently low cost as to be disposable.

A further object of the invention is to provide an endoscopic biopsy device having a simplified, positive means for opening and closing its jaws.

Another object of the invention is to provide an endoscopic biopsy device in which the jaws, when

closed, remain in the closed position until opened by the user.

DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

- FIG. 1 is a fragmented, partly broken away illustration of an endoscopic biopsy device in accordance with the present invention;
- FIG. 2 is a side view of the device as shown in FIG. 1 with the biopsy jaws in an open configuration;
- FIG. 3 is an enlarged sectional illustration of the distal end of the device showing the biopsy jaws in an open configuration;
- FIG. 4 is an illustration similar to FIG. 3 with the biopsy jaws in a closed configuration;
- FIG. 5 is an illustration of the distal end of the device as seen along the line 5-5 of FIG. 4;
- FIG. 6 is an end view of the device as shown in FIG. 3 with the jaws open as seen from the right of FIG. 3;
- FIG. 7 is an exploded illustration of the components at the distal end of the device; and
- FIG. 8 is a further enlarged illustration of the connection between the control wire 14 and the jaw and barb assembly.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As shown in FIGS. 1 and 2, the invention is embodied in a biopsy device having an elongate flexible tubular shaft 10 which may be formed from a stainless steel helical coil 12. A control wire 14, that also may be formed from stainless steel, extends through the lumen 16 (see FIG. 3) defined by the helical coil 12. The control wire 14 is connected to an actuating means 18 at the proximal end of the device by which the physician controls its operation. A pair of biopsy jaws 20 is carried at the distal end of the shaft 10. The jaws 20 are operably associated with the control wire 14 so that they may be closed (FIGS. 4, 5) or opened (FIGS. 2, 3) by operation of the control wire 14. When the jaws 20 are closed, they define a diameter substantially the same as the outer diameter of the shaft 10 so that the entire device will fit slidably through the channel of the endoscope. For ease in description, directions or locations toward the longitudinal axis of the device will be referred to as "inward" while directions away from the longitudinal axis will be referred to as outward. Thus, the biopsy jaws may be considered to swing inwardly when they close and outwardly when they open.

The dimensions of the channel in the endoscope will vary for different types of endoscopes. For example, endoscopes used in gastrointestinal environments typi-

cally have a biopsy channel 2.8 mm in diameter whereas endoscopes for pulmonary use typically have a biopsy channel 2.0 mm in diameter. Additionally, the lengths of such endoscopes varies according to their use. Pulmonary endoscopes are shorter than gastrointestinal endoscopes. By way of further example, the shaft 10 of the present invention may be of the order of between .070" to .080" in diameter and may be between 100 cm to 240 cm in length, depending on the type and size of the endoscope with which it is to be used. Other lengths and diameters may be appropriate for other types of endoscopes which may have different lengths and channel sizes. It may be desirable, in use, to coat the outer surface of the coil 12 with a lubricious material.

5 The diameter of the control wire 14 depends on the length of the device and, possibly, on the type of tissue which the device will be used to sample. The stiffness of the control wire is a function of its diameter. Preferably, the control wire usable for the particular type of endoscope should be the smallest diameter that will operate the jaws 20 so as not to adversely affect the flexibility of the device. By way of example, we have found that a control wire as small as .016" diameter may be effective to operate the jaws in a device 100 cm to 240 cm long.

10 20 25 The control wire preferably is coated with Teflon (polytetrafluoroethylene) to enhance its ability to slide in the coil 12.

As shown in FIGS. 1 and 2, the actuating means 18 includes a stationary member 22 that is attached to the proximal end of the coil 12. The stationary member 22 preferably is provided with a thumb socket 24. The stationary member 22 also is provided, with a longitudinally extending slot 26 that separates and defines a pair of parallel rails 28. A movable slide 30 is provided with a pair of finger holes and is slidably mounted to the rails 28. The proximal end of the coil 12 extends through an opening 32 in the stationary member 22 and guides the control wire 14 to a point of attachment 31 on the slide 30. From the foregoing, it will be appreciated that the proximal end of the device can be operated with one hand, to pull proximally on the control wire 14 or to push it distally. The device is arranged so that pushing on the wire opens the jaws 20 and pulling on the wire 14 causes the jaws 20 to close.

45 50 55 As shown in FIGS. 3-7, the device includes a jaw and barb assembly, indicated generally at 34 (FIGS. 3 and 7), and an asymmetrical tubular clevis indicated generally at 36. The clevis 36 has a proximal end 38 that is securely attached to the distal end of the coil 12 and a distal end having a pair of slots 40, 42 arranged asymmetrically as described in further detail below.

The jaw and barb assembly 34 includes the biopsy jaws 20 which, in turn, have arms 44, cutting cups 46 at the outer ends of the arms 44 and are pivoted to each other their inner ends at a pivot pin 48. Each of the arms may be considered as having a proximal segment 50, an outwardly offset intermediate segment 52 and a distal segment 54, the cutting cup 46 for that jaw being

integrally formed with the distal segment. The jaws may be machined or may be formed by other techniques such as metal injection molding. The arms 44 and cups 46 are formed from stainless steel. The rim of each cup 46 defines a sharpened edge 56. The pivot pin 48 connects the arms at their proximal segments 50. The intermediate segment 52 is offset so that the distal segment 54 and its associated cutting cup 56 will be disposed outwardly of the proximal segment 50.

The device also may include a barb 58 that extends longitudinally of the device. The barb 58 may be formed from a flat sheet of stainless steel interposed between the flat inwardly facing surfaces 60 of the proximal segments 50 of the arms 44. The barb 58 has a proximal end 62 through which the pivot pin 48 is passed and a distal end 64 which is sharpened to a point. The proximal end 62 of the barb is secured, as by an integral extension 66 to the distal end of the control wire 14. The intermediate segment 52 of each of the arms also may be considered as having an inwardly facing camming surface 68 and an outwardly facing camming surface 70 which function in the manner described below.

The distal portion of the asymmetrical tubular clevis 36 is arranged to receive the proximal and intermediate segments 50, 52 of the arms when the biopsy jaws are in their closed configuration as suggested in FIGS. 4 and 5. The distal end of the tubular clevis 36 includes the pair of asymmetrically arranged slots 40, 42. Each of the slots 40, 42 is arranged to receive one of the arms 44, the width of each slot being just sufficient to receive the corresponding width of one of the arms 44. Engagement of the sides of the arms 44 with the facing sides of the slots 40, 42 stabilizes the arms 44 and guides them closely in inward and outward movement with minimal side-by-side movement. This further assures effective cooperative cutting by the inwardly facing sharp edges 56 of the cutting cups 46 when the cups are brought together.

Each of the slots 40, 42 is generally U-shaped and includes a bottom surface 78. The tubular clevis also includes a camming member in the form of a pin 80 attached at its ends to the distal-most end walls 82 of the tubular clevis 36. The pin 80 passes through a longitudinally extending slot 84 in the barb 58 and serves to stabilize the barb in a longitudinally extending position. The slot 84 is sufficiently long to permit the barb 58 to move lengthwise of the shaft 10 together with the jaws 20 as the control wire 14 is operated. The pin 80 is disposed with respect to the inner cam surfaces 68 of the arms 44 so that when the control wire 14 is advanced distally, the distally advancing arms 48 will be urged outwardly as the inner cam surfaces 68 advance against the pin 80. In order to close the jaws, the control wire 14 is retracted proximally. In that motion, the outer cam surfaces 70 bear and slide against the bottom surfaces 78 of the slots 40, 42 to swing the arms 44 inwardly. The foregoing arrangement results in closure of the cups with relatively little longitudinal motion thereby enhanc-

ing a clean cut with minimal tearing of tissue. Thus, the jaws are caused to open by distal movement of the control wire and cooperation of the pin 80 with the inner cam surfaces while closure of the device is effected by proximal retraction of the control wire and resulting cooperation of the outer cam surfaces with the bottom surfaces 78 of the clevis.

The sharp tip of the barb 58 serves to permit the device, with open jaws, to be brought firmly against the surface of tissue to be biopsied and by embedment in the tissue to maintain a fixed position of the jaws with respect to the tissue, even if the tissue is in motion, as is often the case when sampling tissue from a living patient. The jaws then simply may be closed by pulling on the control wire 14, the barb retracting simultaneously with the closure motion.

From the foregoing, it will be appreciated that the invention provides an improved biopsy device having a simplified mechanism and including only a single pivot point. The device lends itself to relatively low cost manufacture and, therefore, is adaptable to disposable use. It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments and equivalents may be apparent to those skilled in the art.

Claims

30. 1. A biopsy device comprising:

an elongate flexible tube (10) having a proximal end and a distal end; a pair of biopsy jaws (20) each having a proximal end and a distal end, the proximal ends of the biopsy jaws (20) being pivoted about a pivot (48) for closing inward and opening outward movement; an actuating member (14) extending through the tube (10) and being connected at its distal end to the pivot (48), the actuating member (14) being controllable from the proximal end of the device to be movable proximally or distally within the tube (10); the jaws (20) having inner (68) and outer (70) camming surfaces; and the distal end of the tube (10) having surfaces engageable with the inner (68) and outer (70) camming surfaces on the jaws (20) to cause the jaws (20) to open when the actuating member (14) is moved in one direction and to close when the actuating member (14) is moved in the opposite direction,

the biopsy device characterized in that each of the jaws (20) has an arm (44) having a proximal segment (50), an outwardly offset intermediate segment (52) extending from the distal end of the inner segment (50), and a distal segment (54) extending from the distal end of the intermediate segment (52) and that the inner (68)

and outer (70) camming surfaces are formed on the inwardly and outwardly facing surfaces of the intermediate segment (52).

2. A biopsy device as defined in claim 1 further characterized by a biopsy cup (46) attached to the distal segment (54) of each arm (44). 5

3. A biopsy device as defined in claim 2 further characterized in that the distal most end of the tube (10) is formed to define a pair of slots (40) and (42), each slot (40), (42) being associated with and adapted to receive a portion of one of the arms (44), the width of each slot (40), (42) corresponding substantially to the width of the arm (44) associated with the slot (40), (42) to enable the arm (44) to move through the slot (40), (42) while proving lateral stability for the arm (44). 10

4. A biopsy device as defined in claim 3 further characterized in that the distal end of the tube (10) has camming surfaces that comprise the bottom (78) of the slots (40), (42) that receive the arms (44), said slot bottoms (78) being engageable with the outer camming surfaces (70); and a transverse member (80) mounted to the distal end of the tube (10) generally parallel to the pivot axis, the transverse member (80) being engageable simultaneously with the inwardly facing camming surfaces (68). 15

5. A biopsy device as defined in claim 2 further characterized in that the proximal segments (50) of the arms (44) are received substantially fully within the distal end of the tube (10) when the jaws (20) are closed thereby locking the jaws (20) in a closed configuration. 20

6. A biopsy device as defined in any one of claims 1-5 further characterized by a barb member (58) comprising a flat elongate plate having a proximal end (62) captured between the jaws (20), the barb plate having a distally extending sharpened end (64) and a stabilizer (84) for maintaining the barb member (58) in a longitudinally oriented attitude. 25

7. A biopsy device as defined in claim 6 further characterized in that the stabilizer (84) comprises an elongate slot (84) formed in the plate. 30

Patentansprüche 50

1. Biopsie-Einrichtung, aufweisend:

ein längliches flexibles Rohr (10) mit einem nahen Ende und einem entfernten Ende; ein Paar von Biopsiezangen (20) mit jeweils einem nahen Ende und einem entfernten Ende, wobei die nahen Enden der Biopsiezangen (20) um einen Drehzapfen (48) schwenkbar sind für eine Einwärts-Schließbewegung und eine Auswärts-Öffnungsbewegung; ein Betätigungssegment (14), das sich durch das Rohr (10) erstreckt und mit seinem entfernten Ende mit dem Drehzapfen (48) verbunden ist, wobei das Betätigungssegment (14) von dem nahen Ende der Einrichtung steuerbar ist, um nah oder entfernt innerhalb des Rohres (10) beweglich zu sein; die Zangen (20) eine innere (68) und eine äußere (70) Nockenoberfläche aufweisen; und das entfernte Ende des Rohres (10) Oberflächen besitzt, die mit den inneren (68) und äußeren (70) Nockenoberflächen an den Zangen (20) in Eingriff gelangen, um die Zangen (20) zum Öffnen zu veranlassen, wenn das Betätigungssegment (14) in einer Richtung bewegt wird und um die Zangen zum Schließen zu veranlassen, wenn das Betätigungssegment in der entgegengesetzten Richtung bewegt wird, wobei die Biopsie-Einrichtung dadurch gekennzeichnet ist, daß jede der Zangen (20) einen Arm (44) aufweist mit einem nahen Segment (50), einem nach außen versetzten Zwischensegment (52), das sich von dem entfernten Ende des inneren Segmentes (50) erstreckt und ein entferntes Segment (54), das sich von dem entfernten Ende des Zwischensegmentes (52) erstreckt, und daß die inneren (68) und äußeren (70) Nockenoberflächen auf den nach innen und außen gerichteten Oberflächen des Zwischensegmentes (52) gebildet sind. 35

2. Biopsie-Einrichtung nach Anspruch 1, ferner gekennzeichnet durch einen Biopsie-Becher (46), der mit dem entfernten Segment (54) eines jeden Armes (44) befestigt ist. 40

3. Biopsie-Einrichtung nach Anspruch 2, ferner dadurch gekennzeichnet, daß das am weitesten entfernte Ende des Rohres (10) geformt ist, um ein Paar von Schlitten (40) und (42) zu definieren, wobei jeder Schlitz (40), (42) einem Teil eines der Arme (44) zugeordnet ist und diese aufnehmen kann, wobei die Breite eines jeden Schlitzes (40), (42) im wesentlichen der Breite des Armes (44) entspricht, und dem Schlitz (40), (42) zugeordnet ist, um dem Arm (44) die Bewegung durch den Schlitz (40), (42) zu ermöglichen, während eine seitliche Stabilität für den Arm (44) vorgegeben wird. 45

4. Biopsie-Einrichtung nach Anspruch 3, ferner dadurch gekennzeichnet, daß das entfernte Ende des Rohres (10) Nockenoberflächen besitzt, die den Boden (78) der Schlitte (40), (42) umfassen, welche die Arme (44) aufnehmen, wobei die Schlitzböden (78) mit den äußeren Nockenoberflä- 55

chen (70) in Eingriff bringbar sind; und ein Querelement (80), das mit dem entfernten Ende des Rohres (10) allgemein parallel zu der Schwenkachse verbunden ist, wobei das Querelement (80) gleichzeitig mit den nach innen gerichteten Nokkenoberflächen (68) in Eingriff bringbar ist.

5. Biopsie-Einrichtung nach Anspruch 2, ferner dadurch gekennzeichnet, daß die nahen Segmente (50) der Arme (44) im wesentlichen vollständig innerhalb des fernen Endes des Rohres (10) aufgenommen werden, wenn die Zangen (20) geschlossen sind, wodurch die Zangen (20) in einer geschlossenen Konfiguration verriegelt werden.

10. 6. Biopsie-Einrichtung nach irgendeinem der Ansprüche 1 bis 5, ferner gekennzeichnet durch ein Widerhakenelement (58), das eine flache längliche Platte mit einem nahen Ende (62) umfaßt, die zwischen den Zangen (20) gefangen ist, wobei die Widerhakenplatte ein entferntes sich erstreckendes geschärfetes Ende (64) aufweist, sowie einen Stabilisator (84) für die Beibehaltung des Widerhakenelements (58) in einer längs ausgerichteten Lage.

15. 7. Biopsie-Einrichtung nach Anspruch 6, ferner dadurch gekennzeichnet, daß der Stabilisator (84) einen in der Platte gebildeten länglichen Schlitz (84) aufweist.

Revendications

1. Pince à biopsie comprenant :

un tube flexible allongé (10) ayant une extrémité proximale et une extrémité distale ; une paire de mâchoires à biopsie (20) ayant chacune une extrémité proximale et une extrémité distale, les extrémités proximales des mâchoires à biopsie (20) pivotant autour d'un pivot (48) vers l'intérieur pour un mouvement de fermeture et vers l'extérieur pour un mouvement d'ouverture ; un élément déclencheur (14) s'étendant à travers le tube (10) et étant relié à son extrémité distale au pivot (48), l'élément déclencheur (14) pouvant être commandé depuis l'extrémité proximale du dispositif pour se déplacer dans la partie proximale ou dans la partie distale à l'intérieur dudit tube (10) ; les mâchoires (20) ayant des surfaces intérieures (68) et extérieures (70) formant cames ; et l'extrémité distale de tube (10) ayant des surfaces aptes à venir en prise avec les surfaces intérieures (68) et extérieures (70) formant cames sur les mâchoires (20) pour faire ouvrir les mâchoires (20) lorsque l'élément de déclenchement (14) est déplacé dans une direction, et pour les faire fermer quand l'élé-

ment déclencheur (14) est déplacé dans la direction opposée.

la pince à biopsie étant caractérisée en ce que chacune des mâchoires (20) comprend un bras (44) ayant un segment proximal (50), un segment intermédiaire décalé vers l'extérieur (52) partant de l'extrémité distale du segment intérieur (50), et un segment distal (54) partant de l'extrémité distale du segment intermédiaire (52), et en ce que les surfaces intérieures (68) et extérieures (70) formant cames sont constituées sur les surfaces orientées vers l'intérieur et vers l'extérieur du segment intermédiaire (52).

15. 2. Pince à biopsie selon la revendication 1, caractérisée encore par une coupelle à biopsie (46) reliée au segment distal (54) de chaque bras (44).

20. 3. Pince à biopsie selon la revendication 2, caractérisée en outre en ce que l'extrémité la plus distale du tube (10) est formée en définissant deux, fentes (40) et (42), chaque fente (40), (42) étant associée à, et apte à recevoir, une partie d'un des bras (44), la largeur de chaque fente (40), (42) correspondant substantiellement à la largeur du bras (44) associé à la fente (40), (42) pour permettre au bras (44) de se déplacer à travers la fente (40), (42) tout en assurant une stabilité latérale du bras (44).

25. 4. Pince à biopsie selon la revendication 3, caractérisée en outre en ce que l'extrémité distale du tube (10) à des surfaces formant cames, qui constituent le fond (78) des fentes (40), (42) recevant les bras (44), et en ce que lesdits fonds (78) des fentes peuvent venir en prise avec les surfaces extérieures formant cames (70) ; et un élément transversal (80) monté à l'extrémité distale du tube (10) généralement parallèle à l'axe de pivotement, l'élément transversal (80) pouvant simultanément venir en prise avec les surfaces formant cames, orientées vers l'intérieur (68).

30. 5. Pince à biopsie selon la revendication 2, caractérisée en outre en ce que les segments proximaux (50) des bras (44) sont regis substantiellement en totalité dans l'extrémité distale du tube (10) quand les mâchoires (20) sont fermées, an bloquant ainsi les mâchoires (20) en configuration fermée.

35. 6. Pince à biopsie selon l'une quelconque des revendications 1-5, caractérisée en outre par un élément de lamelle (58) constitué par une plaque plane, allongée, ayant une extrémité proximale (62) retenue entre les mâchoires (20), la lamelle plane ayant une extrémité pointue (64) s'étendant dans la direction distale, et un stabilisateur (84) pour maintenir l'élément de lamelle (58) avec une attitude orientée

dans la direction longitudinale.

7. Pince à biopsie selon la revendication 6, caractérisée en outre au ce que le stabilisateur (84) comporte par une fente allongée (84) formée dans la plaque. 5

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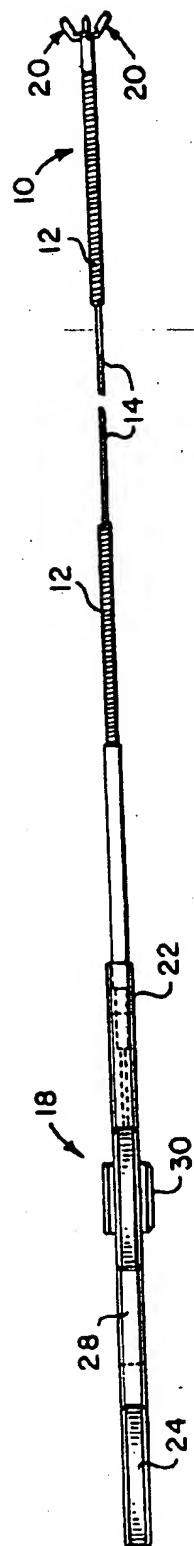
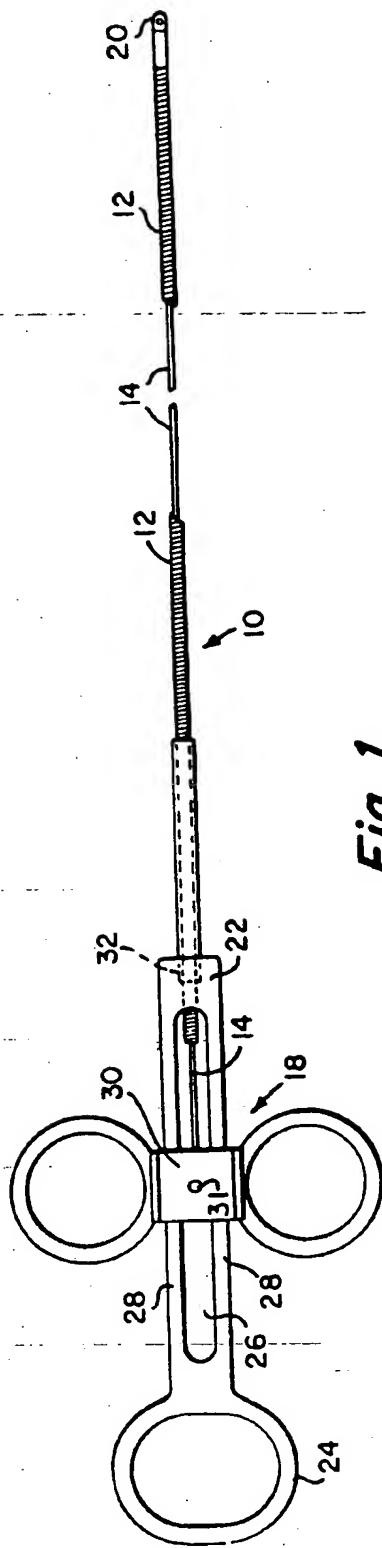
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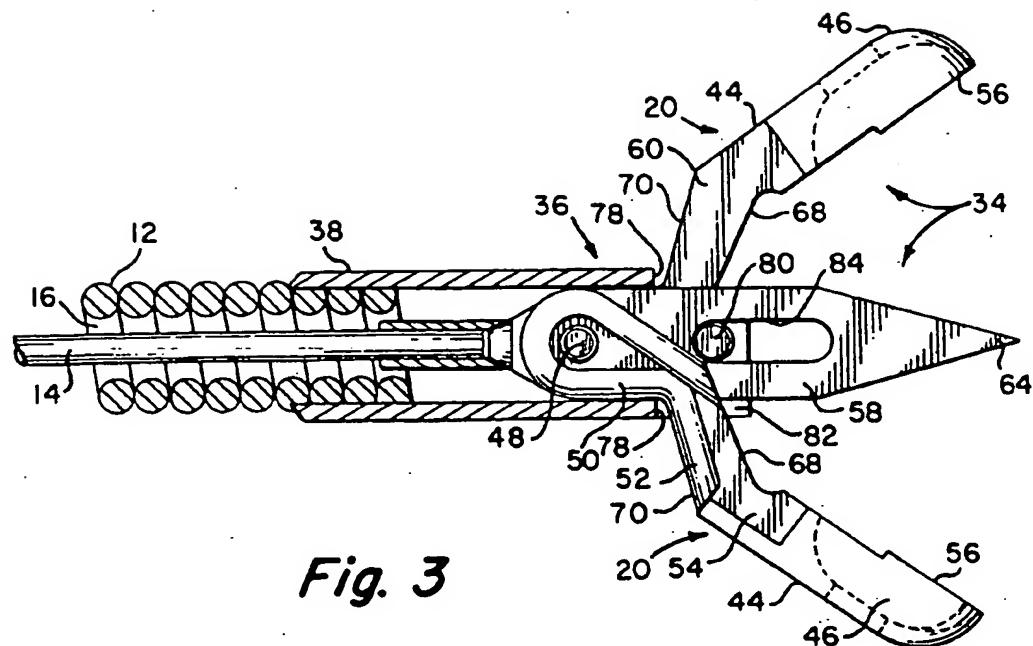


Fig. 3

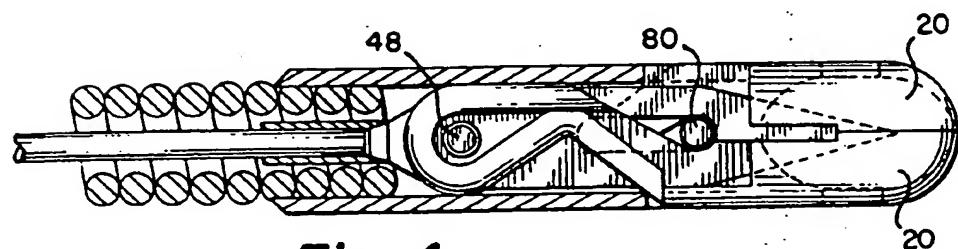


Fig. 4

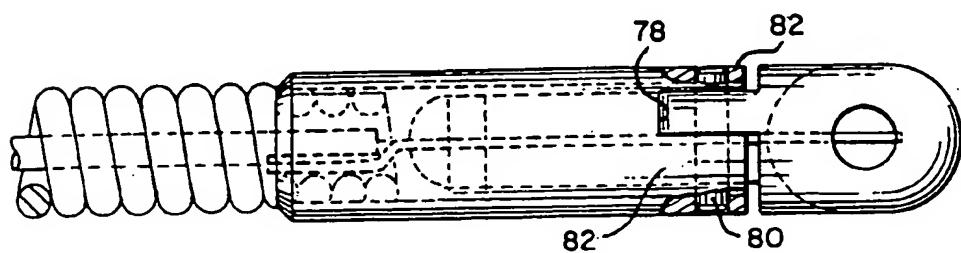


Fig. 5

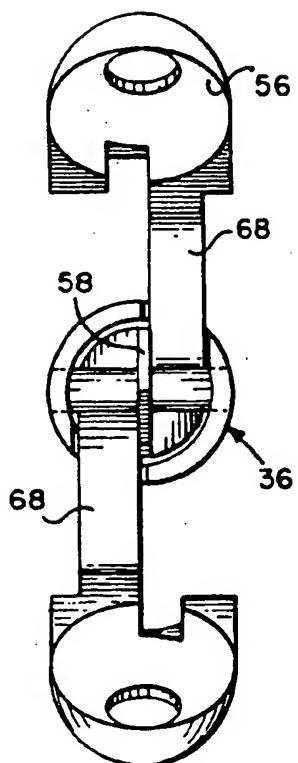


Fig. 6

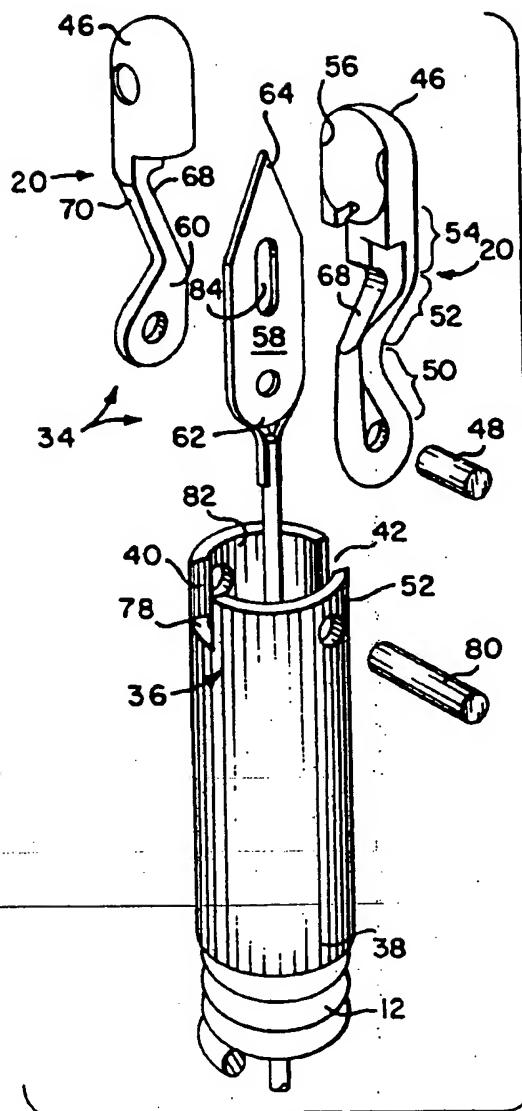


Fig. 7

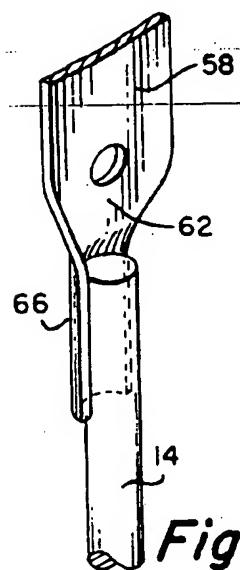


Fig. 8